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✓ Facility

✓ Products Listing

Annual Registration Successful

Facility: ORGANOGENESIS INC., Saint Petersburg, Florida, UNITED STATES

You have successfully updated your registration and listing information for 2024.

Your registration will be valid through Dec 31, 2024.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2024.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9008375.

Facility Information

Registration Number:

3012100095

Initial Importer:

N

Facility Name:

ORGANOGENESIS INC.

Legal Name:

Address:

12495 34th Street North, Suite D

Saint Petersburg, Florida, 33716, UNITED STATES

DUNS Number:

079896008

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:

9008375

Contact Name:

Patrick R Bilbo

Company:
ORGANOGENESIS INC.

Address: 150 Dan Road, --
Canton, MASSACHUSETTS, 02021, UNITED STATES

Telephone:
781 - 4011155

Fax:
781 - 4011280

E-mail: pbilbo@organo.com

DUNS Number:
152165817

Official Correspondent Information

Contact Name:
Patrick R Bilbo

Company:
ORGANOGENESIS INC.

Address: 150 Dan Road, --
Canton, MASSACHUSETTS, 02021, UNITED STATES

Telephone:
781 - 4011155

Fax:
781 - 4011280

E-mail: pbilbo@organo.com

DUNS Number:
152165817

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D464444	K181315		FRO	Dressing, wound, drug	Repackager/Relabeler Complaint File Establishment
D464443	K152970		FRO	Dressing, wound, drug	Complaint File Establishment Repackager/Relabeler
D458983	K122325		KGN	Wound dressing with animal-derived material(s)	Complaint File Establishment Repackager/Relabeler
D458985	K060804		FRO	Dressing, wound, drug	Repackager/Relabeler Complaint File Establishment
D464223		510(k) exempt	NAE	Dressing, wound, hydrogel without drug and/or biologic	Repackager/Relabeler Complaint File Establishment

D458988		510(k) exempt	FQM	BANDAGE, ELASTIC	Complaint File Establishment Repackager/Relabeler
D458991		510(k) exempt	NAB	Gauze / sponge,nonresorbable for external use	Complaint File Establishment Repackager/Relabeler
D458990		510(k) exempt	KGX	Tape and bandage, adhesive	Repackager/Relabeler Complaint File Establishment
D479747	K142153		CAF	Nebulizer (direct patient interface)	Repackager/Relabeler Complaint File Establishment
D464254		510(k) exempt	NAD	Dressing, wound, occlusive	Repackager/Relabeler Complaint File Establishment
D464250		510(k) exempt	NAC	Dressing, wound, hydrophilic	Repackager/Relabeler Complaint File Establishment
D484959	K910944		KGN	Wound dressing with animal-derived material(s)	Repackager/Relabeler Complaint File Establishment
D433711	K120181		FRO	Dressing, wound, drug	Repackager/Relabeler Complaint File Establishment

Date of Initial Registration: 2021-01-19 15:45:23,0